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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,635	12/14/2001	Friedhelm Eisenbeiss	MERCK 2335	9780

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EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,635

Applicant(s)

EISENBEISS ET AL.

Examiner

Kaj K Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005 and 30 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The numerous amendments to the specification are approved of and the examiner has withdrawn all outstanding objections to the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 5 was previously found to be indefinite because it merely set forth uses of the analytical unit of claim 1 (see previous office action). Applicant has attempted to rectify the situation by now actually claiming the uses in structural form. This raises a new issue of indefiniteness. In particular, these various depletors, extractors, separators, or enrichers don't appear to be structural elements *per se*, but are uses of the set forth analytical unit. However, the applicant is now claiming an analytical unit of claim 1 *further comprising*, as an example, a depletor. A depletor would appear to be what the applicant is utilizing the analytical for and not a separately claimable element. Similar confusion is associated with the other set forth elements of claim 5.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al (USP 5,989,402) in view of either Manz et al (USP 6,280,589) or Effenhauser et al (Anal. Chem. 1993, 65, pp. 2637-2642). Manz and Effenhauser are being cited and relied on for the first time with this office action. Their use here was necessitated by the amendment to the claims.

7. Chow discloses an analytical unit comprising a flow through unit 10 made of plastic (col. 6, lines 1-21) having a microstructured channel system (col. 6, lines 22-33). Chow further discloses an adaptor chamber 206 for reversibly receiving the flow through unit (paragraph bridging col. 9 and 10). The reservoirs 24 of the flow through unit hold fluid and constitute a “fluidic supply” giving the claim language its broadest reasonable interpretation. Chow also discloses a power supply and at least one detector (col. 7, lines 1-15 and col. 17, lines 15-65).

8. With respect to amended claim 1, Chow does not disclose the use a sample channel section having openings at two ends to define a volume of sample therebetween. Manz discloses in an alternate flow through unit that sample channel 27 can comprise two ends 13 and 14 that have fluid connections. Said sample channel thereby defines a volume of fluid to be analyzed. See abstract, fig. 1 and 4 and col. 5, lines 5-16. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Manz for the analytical unit of Chow in order to precisely control the size of samples to be analyzed.

9. Effenhauser teaches analogous subject matter to that of Manz. See fig. 1 and 2 and p. 2638, first column, second paragraph. It would have been obvious to one of ordinary skill in the

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art at the time the invention was being made to utilize the teaching of Effenhauser for the analytical unit of Chow in order to precisely control the size of samples to be analyzed.

10. With respect to claim 2, Chow, Manz and Effenhauser all teach the presence of waste channels that can branch off having legs that extend from the branching point. See Chow fig. 1; Manz, fig. 1; and Effenhauser, fig. 1. A waste channel would read on the claimed “discharging apparatus” giving the claim language its broadest reasonable interpretation. With respect to the claimed “Y branch”, the examiner is presuming the applicant is referring to where one channel branches into two channels and not referring to a channel that resembles the letter “Y” (especially considering that none of the applicant’s shown “Y” branches in the figures resemble the letter “Y”). In view of that, Chow, Manz, and Effenhauser all show the set forth Y branching. The detector is clearly upstream of the waste channels. With respect to the switching apparatus, see Chow, col. 7, line 52 through col. 8, line 38.

11. With respect to claim 3, it would appear that claim 3 no longer requires the presence of a peristaltic pumps, syringes or syringe pumps, but merely inlets and outlets that could be coupled to peristaltic pumps, syringes or syringe pumps. Effenhauser already teaches the use of pressure syringe to load solution into the various reservoirs. See p. 2638, final paragraph of the second column. See also col. 1, lines 42-45 of Manz.

12. With respect to claim 4, Chow discloses electrodes in the various channels. See col. 7, line 52 through col. 8, line 38. With respect to the channels being for isotachophoretic separation, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

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13. With respect to amended claim 5, it would appear this claim still just constitutes the intended use of the analytical unit of claim 1 (see 112 rejection above) and the intended use need not be given further due consideration in determining patentability. However, Chow is utilized for analyte separation.

14. With respect to claim 6, the various features of the sample channel of Manz and Effenhauser would meet the broadly defined "constructions" for fluid connections.

15. With respect to claim 7, the various channels shown on fig. 1 and 2A of Chow would meet the defined "additional channel sections". Containing buffer solutions is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

16. With respect to claims 8 and 9, assuming a sample channel with 100 μm sides and 3 cm length (see Manz, col. 6, lines 54-56 and col. 7, lines 41-47), that would result in a sample volume of 0.3 μl . Alternatively, even if the examiner were in error with his calculation, choosing the desired volume for the sample channel would have required only routine skill in the art. Larger volumes than those disclosed by Manz or Effenhauser would have provided more detectable analyte thereby improving the signal to noise ratio.

17. Claim 3 in the alternative is rejected under 35 U.S.C. 103(a) as being unpatentable over Chow and either Manz or Effenhauser as applied to claim 1, and in further view of Blankenstein et al (Biosensors & Bioelectronics, vol. 13, 1998, pp. 427-438).

18. If amended claim 3 were interpreted as actually requiring both the presence of a peristaltic pump, syringe or syringe pump and the use of the syringes of Manz or Effenhauser were not interpreted as meeting this limitations, Blankenstein discloses in an alternate

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microfluidic device that other means of moving fluid are also useable with microfluidics including the use of syringe pumps (see fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Blankenstein for the analytical unit of Chow and either Manz or Effenhauser because the substitution of one known means for moving fluid for another requires only routine skill in the art.

19. The examiner has withdrawn the alternative rejection of claims 1, 2, 4 and 5 over Chow and Blankenstein because it is now clear that "fluidic connection" of claim 1 does not require the presence of one of a peristaltic pump, syringe or syringe pump.

Response to Arguments

20. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection necessitated by the applicant's amendment.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
February 16, 2005



KAJ K. OLSEN
PRIMARY EXAMINER